UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HENRYK TAPER, ANNE FRIPPIAT, JAN VAN LOO, and MARCEL ROBERFROID

Appeal No. 2006-2235
Application No. 09/700,573

ON BRIEF

Before ADAMS, GREEN, and LEBOVITZ, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 21-33 and 35-40. Claims 21, 24, and 35 are representative of the claims on appeal, and read as follows:

21. Pharmaceutical composition characterized by comprising a combination of an effective dose of inulin and of an anti-metabolic anti-cancer drug, wherein said inulin and said anti-metabolic anti-cancer drug in combination provide a synergistic anti-cancer therapeutic effect to a human or non-ruminating animal undergoing treatment for cancer.

24. Pharmacuetical composition according to claim 21, wherein the anti-cancer drug is selected from the group consisting of methotrexate, cytarabin, fluorouracil, mercaptopurin, thioguanin, azathioprin and hydroxycarbamide.

35. Method for the treatment of cancer in a human or in a non-ruminating mammal comprising administering to said being in need of such treatment an effective amount of a pharmaceutical composition as defined in claim 21.

Claims 35-40 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to enable the full scope of the claims. In addition, claims 21-33 and 35-42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Roberfroid.[1] After careful review of the record and consideration of the issues before us, we affirm the rejection of all the claims under § 102, but reverse the rejection made under 35 U.S.C. § 112, first paragraph.

BACKGROUND

The invention is drawn to a pharmaceutical composition comprising a combination of a non-digestible carbohydrate, such as inulin, and an anti-cancer drug. See Specification, page 1. According to the Specification,

> Inulins are D-fructans consisting of water soluble chains of fructose units . . ., but they are composed of chains in which the fructose units are connected to each other or exclusively by β(2-1) fructosyl-fructose linkages. . . . [I]nulin-type polyfructose chains often end in a glucose unit. Inulin mostly occurs as a polydisperse mixture of linear polyfructose molecules, as for example inulin from chicory, but inulin can also occur as a polydisperse mixture of

[1] Roberfroid et al. (Roberfroid), EP 0692252 A1, published January 17, 1996

> branched polyfructose molecules, as for example inulin from dahlia and inulin from agave.

Id. at 4.

The specification acknowledges that EP 0 692 252 A1 discloses that inulin has "a preventative effect on carcinogenisis and an inhibitory effect on the growth of cancer in mammals, particularly mammary cancer," and discloses its use with conventional chemotherapeutic agents. Id. at 6. The specification asserts, however, that EP 0 692 252 A1 is silent "about possible synergistic effects between a non-digestable fructan-type carbohydrate and conventional anti-cancer drugs." Id.

An example of an anti-cancer drug is an anti-metabolic anti-cancer drug. See id. at 8. Anti-metabolic chemotherapeutic dugs "embraces products which compete with the normal metabolites of nucleic acids in cell synthesis and in cell growth pathways. This class of drugs is comprising methotrexate, cytarabin, fluorouracil, mercaptopurin, thioguanine, azathioprin and hydroxycarbamide." Id.

Moreover, according to the specification, "[t]he composition according to the invention is suitable in the first place for the treatment of cancer in humans. However, it is also suitable too for the treatment of cancer in non-ruminant mammals, such as for example horses, rabbits, dogs and cats." Id.

> The effective dose of the synergistic combination of inulin and anti-metabolic anti-cancer drug may depend on various factors, including the affected being, a human or species of non-ruminating mammals, its age and physical condition, the kind and stage of development of the cancer, the kind of inulin and of anti-cancer drug, and the method of administration of the synergistic combination. The effective dose, the optimal galenic form and unit

> dose, and the way of administration can be determined by the skilled person following conventional methods.

Id. at 9.

Finally, the specification presents data demonstrating a synergistic effect for the combination of inulin with either 5-fluorouracil or methotrexate in tumor bearing mice. See id. at 14-15.

DISCUSSION

Claims 12-30 and 32-34 stand rejected under 35 U.S.C. § 112, first paragraph, "because the specification, while being enabling for the treatment of certain cancers, does not reasonably provide enablement for 'treatment of cancer' in general." Examiner's Answer, page 3.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided

"acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

While the examiner engages in a Wands analysis, see In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988) (noting that facts that should be considered in determining whether a specification is enabling include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims), the examiner's primary concern appears to be that "there is no known anti-cancer agent, which is effective against all cancers." Examiner's Answer, page 4.

The examiner states, relying on In re Brana, 51 F.3d, 1560, 34 USPQ2d 1436 (Fed. Cir. 1995):

> While the state of the art [is, sic] relatively high with regard to the treatment of specific cancers with specific agents, it has long been underdeveloped with regard to the treatment of cancers broadly. In Particular [sic], there is no known anti-cancer agent which is effective against all cancers.

Id. According to the examiner, "a considerable amount of in vitro empirical testing is required with no prior expectation being present, before a candidate anticancer agent can be considered useful against any particular cancer type." Id. The examiner also cites Gerson[2] to support the proposition that

[2] Gerson et al. (Gerson), US 6,465,448, issued October 15, 2002

"[c]ombination therapies while desirable are a hit or miss proposition." Id. at 5. The examiner, however, provides no evidence to support the above as to the specifically claimed components of the composition, i.e., inulin and an anti-metabolic anti-cancer drug. Moreover, as noted by appellants, the claimed combination requires an anti-metabolite chemotherapeutic agent, which are known to be useful in the treatment in different types of cancers. See Appeal Brief, pages 13-15.

The examiner also asserts that the specification provides no guidance as to which cancers will respond to the treatment, and that "[t]he lack of adequate guidance from the specification or prior art with regard to the actual treatment of all cancers in a mammal with the claimed combination fails to rebut the presumption of unpredictability extent in this art." Examiner's Answer, page 5. The examiner thus concludes that "[a]bsent a reasonable prior expectation of success using a specific chemotherapeutic agent/combination to treat any type of cancer, one skilled in the at would have to extensively test many various tumor types." Id.

Again, the examiner has provided no evidence or scientific reasoning to support those assertions, and thus has not met his burden in demonstrating that the specification fails to enable the full scope of the claimed subject matter. In addition, "any type of cancer" is not the proper standard as a claim may encompass inoperative embodiments and still meet the enablement requirement

of 35 U.S.C. § 112, first paragraph. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), In re Cook, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971).

Therefore, as the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first paragraph, we are compelled to reverse the rejection.

Claims 21-33 and 35-42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Roberfroid. Since the claims stand or fall together, see Appeal Brief, page 4, we focus our analysis on independent claim 21.

According to the rejection:

> [Roberfroid] teaches the use of inulin or oligofructose in combination with an antimetabolite such as methotrexate and fluorouracil for the treatment of cancer. See the abstract and page 3, lines 5-8 and lines 15-16. The above reference makes clear that the claimed components have previously used in combination.

Examiner's Answer, page 6.

We recognize that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that the examiner has set forth a prima facie case of anticipation, and the rejection is affirmed.

Claim 21 is drawn to a pharmaceutical composition characterized by comprising a combination of an effective dose of inulin and of an anti-metabolic anti-cancer drug, wherein said inulin and said anti-metabolic anti-cancer drug in combination provide a synergistic anti-cancer therapeutic effect to a human or non-ruminating animal undergoing treatment for cancer. As the combination can be administered to humans and to non-ruminating animals from as small as a rabbit or cat to as large as a horse, the composition reads on a large range of amounts of inulin and the anti-metabolic cancer drug present in the composition.

Roberfroid teaches a combination of inulin with a conventional chemotherapeutic product, of which antimetabolites are one of a list of six specific classes of compounds listed. Thus, we find that Roberfroid fairly teaches a combination of inulin and an antimetabolite, such as methotrexate and fluorouracil. See, e.g., In re Petering, 301 F.2d 676, 681-82, 133 USPQ 275, 280 (CCPA 1962) (disclosure of a small genus is equivalent to disclosure of each member of the genus).

Moreover, the fact that the claim is drawn to a "synergistic combination" does not render the claim patentable, as Roberfroid teaches the same combination as is being instantly claimed, the combination of inulin with an antimetabolitic chemotherapeutic agent. "[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the claimed

compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art." Id. at 709, 15 USPQ2d at 1658.

Appellants argue that Roberfroid fails to teach the claimed combination and the claimed synergy. See Appeal Brief, page 7. According to appellants, Roberfroid teaches the use of inulin in the treatment of breast cancer, along with conventional chemotherapeutic products, of which antimetabolites is one of a laundry list. See id. at 7. Appellants contend further that Roberfroid is "merely a generic disclosure," and that "[n]o specific mention of a combination of inulin/oligofructose and an anti-metabolic anti-cancer product is disclosed," much less "a possible synergistic effect from the appropriate selection, method of selection, or basis of selection of inulin and an anti-metaboloc anti-cancer drug." Id. at 8.

Appellants argue further that Example 7 of Roberfroid discusses determining a potential synergistic effect between inulin and doxorubicine (an anti-mitotic antibiotic), but is silent as to the result. See Appeal Brief, page 8. Thus, according to appellants, there is no teaching in Roberfroid of a synergistic effect between inulin and a chemotherapeutic agent. See id.

Based on the above, appellants contend that Roberfroid "does not disclose a combination of inulin/oligofructose and 'an anti-metabolic drug,' but rather at best discloses a combination of inulin/oligofructose and an 'anti-mitotic

antibiotic,' being the only substantiated combination of inulin/oligofructose and a chemotherapeutic product disclosed in [Roberfroid]." Id. at 9.

Appellants arguments are not found to be convincing. As discussed above, Roberfroid teaches a combination of inulin with six named classes of anti-chemotherapeutic agents, of which antimetabolitic agents being one. Thus, we find that Roberfroid fairly teaches all of the combinations, including the claimed combination. A reference need not have described an actual reduction to practice of an invention in order to serve as an anticipatory reference. See In re Siveramakrishnan, 673 F.2d 1383, 1384, 213 USPQ 441, 442 (CCPA 1982); In re Donohue, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985).

As to the claimed synergy, again as dicussed above, when a claimed composition is not novel it is not rendered patentable by recitation of properties, such as synergy, whether or not these properties are shown or suggested in the prior art.

Appellants also argue that the biological arts are unpredictable. See Appeal Brief, pages 9-10. The instant invention, appellants assert, is drawn to the combination of inulin and anti-metabolic cancer drugs, which combination is neither disclosed nor suggested by Roberfroid. See id. at 10. In addition, the addition of inulin "clearly enhances the anti-cancer effects of anti-metabolite anti-cancer drugs," and the therapeutic effect of fluorouracil and inulin is higher than the sum of the effects of the components separately. Id. Thus, appellants assert, "the properties of a composition according to the present claimed

invention are both novel and unexpected in view of the prior art," id. at 10-11, and that "one skilled in the art could not predict or expect that a particular combination of inulin/oligofructose and a particular class of anti-metabolite anti-cancer chemotherapeutic products would present a synergistic anti-cancer effect," id. at 11.

Again, appellants arguments are not found to be convincing for the reasons already stated. Roberfroid teaches a composition comprising inulin and an anti-metabolic chemotherapeutic agent, and thus anticipates the composition of claim 21. As the compositions appear to be the same, the burden is on appellants to demonstrate that they are different. The fact that the combination provides a synergistic effect is an inherent property, and again, does not render an old composition again patentable.

CONCLUSION

Because the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first paragraph, the rejection of claims 35-40 under that section of the statute is reversed. However, we affirm the rejection of all the claims on appeal under 35 U.S.C. § 102 as being anticipated by Roberfroid.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Donald E. Adams)
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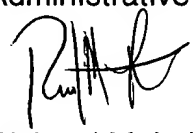
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